DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 03N–0059]

Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a public docket for information relevant to the agency's current good manufacturing practice (CGMP) initiative concerning the regulation of pharmaceutical manufacturing and product quality. This action is intended to ensure that all information submitted to FDA on the CGMP initiative regarding a risk-based approach to the regulation of pharmaceutical manufacturing and product quality is available to all interested persons in a timely fashion.

ADDRESSES: The public dockets are located in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The public dockets can be accessed directly under the docket number provided and on the agency's site at http://www.fda.gov/ohrms/dockets.

FOR FURTHER INFORMATION CONTACT: Maureen A. Hess, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5461.

SUPPLEMENTARY INFORMATION:

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I. Background

On August 21, 2002, FDA announced that it is undertaking a significant new initiative to enhance the regulation of pharmaceutical manufacturing and product quality. The initiative entitled "Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach," applies to veterinary drugs and human drugs, including biological drug products. Additional detailed information describing the scope and purpose of the initiative can be found on the Internet at www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html. FDA has received recommendations on how the agency should implement various aspects of, as well as, the overall CGMP initiative and encourages further recommendations. To provide timely public access to these recommendations, FDA is establishing a public docket through which interested persons can have access to these recommendations and other information submitted to FDA. FDA expects to place submissions it receives on this initiative in the public docket.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the CGMP initiative. Submit a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two hard copies of any mailed comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received

comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 21, 2003

February 21, 2003.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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